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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,034	08/05/2002	Preeti G. Lal	PF-0731 USN	9342

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INCYTE CORPORATION
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,034	LAL ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group A, claim(s) 1-7, 9, 11-14, and 16-17, drawn to an isolated polypeptide, an isolated polynucleotide, a recombinant cell, a method for producing the polypeptide, and a method for detecting a target polynucleotide.

Group B, claim(s) 7-8, drawn to a host cell transformed with a recombinant polynucleotide and a transgenic organism comprising a recombinant polynucleotide.

Group C, claim(s) 10, drawn to an isolated antibody which specifically binds to a polypeptide.

Group D, claim(s) 15, drawn to a method for detecting a target polynucleotide in a sample.

Group E, claim(s) 18 and 22, drawn to a method for treating a disease or condition comprising administering to the patient a polypeptide composition.

Group F, claim(s) 19 and 22, drawn to a method for screening a compound for effectiveness as an agonist/antagonist of a polypeptide.

Group G, claim(s) 20, drawn to a composition comprising an agonist compound.

Group H, claim(s) 21, drawn to a method for treating a disease or condition comprising administering an agonist composition.

Group I, claim(s) 23, drawn to a composition comprising an antagonist compound.

Group J, claim(s) 24, drawn to a method for treating a disease or condition comprising administering an antagonist composition.

Group K, claim(s) 25, drawn to a method for screening for a compound that modulates the activity of the polypeptide comprising combining the polypeptide with a test compound and detecting binding of the polypeptide to the test compound.

Group L, claim(s) 26, drawn to a method for screening for a compound that modulates the activity of the polypeptide comprising combining the polypeptide with a test compound, assessing the activity of the polypeptide, and comparing the activity of the polypeptide in the presence and absence of the test compound.

Group M, claim(s) 27, drawn to a method for screening a compound for effectiveness in altering expression of a target polynucleotide.

Group N, claim(s) 28, drawn to a method for assessing toxicity of a test compound.

2. The inventions listed as Groups A-N do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group A recites the technical feature of a polypeptide, the polynucleotide encoding the polypeptide, the process of making the polypeptide, and a method for detecting a target polynucleotide, which is not required by the other products and methods of Groups B-N.

Group B recites the technical feature of an animal or host cell transformant, which is not required by the other products of Groups A, C, G, and I.

Group C recites the technical feature of an isolated antibody, which is not required by the other products of Groups A, B, G, and I.

Group D recites the technical feature of amplifying a target polynucleotide or fragment using PCR and detecting the presence of absence of amplified target polynucleotide, if present, which is not required by the other methods of Groups A, E-F, H, and J-N.

Group E recites the technical feature of administering a polypeptide composition to a patient, which is not required by the other methods of Groups A, D, F, H, and J-N.

Group F recites the technical feature of screening a compound for effectiveness as an agonist/antagonist of a polypeptide, which is not required by the other methods of Groups A, D-E, H, and J-N.

Group G recites the technical feature of a composition comprising an antagonist, which is not required by the other products of Groups A-C and I.

Group H recites the technical feature of administering an agonist composition to a patient, which is not required by the other methods of Groups A, D-F, and J-N.

Group I recites the technical feature of a composition comprising an agonist, which is not required by the other products of Groups A-C and G.

Group J recites the technical feature of administering a composition comprising an agonist, which is not required by the other methods of Groups A, D-F, H, and K-N.

Group K recites the technical feature of combining the polypeptide with a test compound and detecting binding of the polypeptide to the test compound, which is not required by the other methods of Groups A, D-F, H, and J.

Group L recites the technical feature of combining the polypeptide with a test compound, assessing the activity of the polypeptide, and comparing the activity of the polypeptide in the presence and absence of the test compound, which is not required by the other methods of Groups A, D-F, H, and J-K.

Group M recites the technical feature of exposing a sample comprising the target polynucleotide to a compound and detecting the altered expression of the polynucleotide, which is not required by the other methods of Groups A, D-F, H, and J-L.

Group N recites the technical feature of treating a sample containing nucleic acids with a test compound, hybridizing the nucleic acids with a probe, quantifying the amount of hybridization complex formed, and comparing the amount of hybridization complex in treated and untreated biological samples, which is not required by the other methods of Groups A, D-F, H, and J-M.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-34, claim(s) 1-28, in part, drawn to one polypeptide (SEQ ID NOs: 1-2, 4-16, 18-25, or 27-37). For example, if Group 3 is elected, the claims will be searched to the extent that they read on SEQ ID NO: 4.

Groups 35-68, claim(s) 1-28, in part, drawn to one polynucleotide sequence (SEQ ID NOs: 38-39, 41-53, 55-62, or 64-74). For example, if Group 37 is elected, the claims will be searched to the extent that they read on SEQ ID NO: 41.

4. The inventions listed as Groups 1-34 and 35-68 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims 1-28 broadly encompass the amino acid sequences of any polypeptide. The amino acid sequences of Groups 1-34 are different lengths, composed of different amino acids, and are structurally and functionally unrelated, each to each other. Accordingly, each of the different protein sequences recited in claims 1-28 are not so linked under PCT Rule 13.1 and are thus placed in 34 different inventive Groups numbered 1-34, respectively.

Claims 1-28 broadly encompass a polynucleotide sequence. The nucleotide sequences of Groups 35-68 are different lengths, composed of different nucleic acids, and are structurally and functionally unrelated, each to each other. The nucleic acid sequence imparts structural and functional differences in each gene which affect properties such as expression levels, tissue specific expression patterns, mRNA half lives, cellular localization of the gene product, etc. Furthermore, each gene encodes a different protein product which is not sufficiently linked by structural or functional features. Accordingly, each of the different nucleotide sequences recited in claims 1-28 are not so linked under PCT Rule 13.1 and are thus placed in different inventive Groups numbered 35-68, respectively.

In order to be fully responsive, Applicant must select one from Groups A-N, one from Groups 1-34, and one from Groups 35-68. Applicant is advised that A-N, 1-34, and 35-68 are not species election requirements; rather, each of A-N, 1-34, and 35-68 is a restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

BEB
Art Unit 1647
22 March 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER